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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/893,510	06/29/2001	Peter Forsell	2333-72	3159

23117 7590 01/07/2004

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EXAMINER

MCDERMOTT, CORRINE MARIE

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/07/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/893,510

Applicant(s)

FORSELL, PETER

Examiner

Crystal M Gilpin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) 40-45, 52-60 and 68-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39, 46-51, 61-67 and 93-99 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of claims 1-39, 46-51, 54, 61-67, 71-90 and 93-99 in Paper No. 7 is acknowledged.

Examiner contends that claims 54 and 61-67 are drawn to a non-elected species because of the additional element of the wireless remote control, which is not included in the embodiment of Figure 5. Therefore, only claims 1-39, 46-51, 61-67 and 93-99 have been examined.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Specification***

1. The disclosure is objected to because of the following informalities:

Page 16, Line 32: Reference is made to item number 36 in Figure 5, however there is no Reference number 36 in Figure 5.

Appropriate correction is required.

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2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Correction of the following is required:

Claim 39 is objected to because of the following informalities: Claim 39 recites a rechargeable battery and this language is not supported by the specification.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lue et al.  
(USPN 4,739,764).

Regarding claim 1, Lue et al. discloses a device and method for electrically stimulating the nerves of the muscles that control bowel evacuation to increase the tonus thereof (Column 2, Lines 5-10 and Lines 37-40).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 2-4, 6-12, 46, 47, 54, 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al. (USPN 4,739,764) in view of Benderev (USPN 5,782,745).

Regarding claims 2-4 and 6-12, Lue et al. disclose an intestine dysfunction or incontinence treatment apparatus, but they lack the teaching of a source of energy and a control device. Benderev teaches of a urinary and fecal incontinence device that includes an implantable electric power supply as a source of energy, a battery (Column 2, Lines 63-67) and a control device, controllable from outside the patient's body (Column 3, Lines 9-13) so that the timing, duration, repetitions and frequency of the device can be adjusted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lue et al. to have a power source for the device and a remote control for the purpose of adjusting the settings of the electrical conductors.

3. Claims 15-17, 20-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al. (USPN 4,739,764) in view of Sultan (USPN 6,135,945).

Regarding claims 15-17, 20-23 and 25, Lue et al. disclose an intestine dysfunction or incontinence treatment apparatus, but they lack the teaching of a sensor for sensing at least one physical parameter of the patient. Sultan teaches of an anti-incontinence device that includes a sensor for sensing the pressure in the intra-abdominal cavity so that the device will activate when the pressure rises (Column 3, Lines 20-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lue et al.

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to have a sensor for sensing at least one physical parameter of the patient, as taught by Sultan for the purpose of activating the device based on the physical condition of the patient.

4. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al. (USPN 4,739,764) in view of Sultan (USPN 6,135,945) as applied to claims 15 and 21-23 above, and further in view of Suda et al. (USPN 5,978,712).

Regarding claim 24, Lue et al. as modified by Sultan teach of incontinence devices but they lack the teaching of an external control unit that stores data. Suda et al. teach of a control unit that is worn outside the patient (Column 5, Lines 8-12) and is capable of storing information on physical parameters (Column 4, Lines 29-56) so that the patient's history and progress can be analyzed at a later time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lue et al. to have the device include an external control unit that stores information about the patient for later analysis by the patient's doctor.

5. Claims 26-34 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al. (USPN 4,739,764) in view of Benderev (USPN 5,782,745) as applied to claims 2-4, 6-12, 46 and 47 above, in further view of Sultan (USPN 6,135,945) and further in view of Suda et al. (USPN 5,978,712).

Regarding claims 26-34, Lue et al. as modified by Benderev teach of incontinence devices but they lack the teaching of an implantable programmable control device. Sultan teaches of an anti-incontinence device with a control unit, used to switch the device on and off, that is implantable (Column 2, Lines 46-58). Suda et al. teach of an incontinence device that has a programmable control unit to set up the parameters for the stimulation signals (Column 5,

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Lines 47-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lue et al. to have an implantable control unit, as taught by Sultan for the purpose of switching the device on and off, and a programmable control unit as taught by Suda et al. for the purpose of setting the parameters for the stimulation signals.

Regarding claims 49-51, Benderev teaches of an internal electric source of energy, but both Lue et al. and Benderev lack the teaching of an implantable switch. Sultan teaches of an anti-incontinence device with a switch for controlling the device implanted under the skin (Column 2, Lines 46-48 and Column 8, Lines 5-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lue et al. to have a switch implanted under the skin, as taught by Sultan for the purpose of turning the device on and off.

6. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al. (USPN 4,739,764) in view of Benderev (USPN 5,782,745) as applied to claim 2 above, and further in view of Suda et al. (USPN 5,978,712).

Regarding claim 35, Lue et al. teach of an incontinence device and Benderev teaches that or using a remote with the device but they both lack the teaching of an external source of energy. Suda et al. teach of an incontinence device where the controlling unit, including the power source (Figure 1, Reference #8) is external to the body (Column 5, Lines 8-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lue et al. to have a remote control, as taught by Benderev, for

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controlling the external power source, as taught by Suda et al. to provide energy to the stimulation device.

7. Claims 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al. (USPN 4,739,764) in view of Benderev (USPN 6,135,945) as applied to claims 49-51 above, in further view of Sultan (USPN 6,135,945) and further in view of Leysieffer et al. (USPN 6,537,200).

Regarding claim 61-64, Lue et al. disclose an incontinence device, Benderev teaches the use a remote control with the device, and Sultan teaches the use of an "on"/ "off" switch. However they all lack the teaching of a device that transforms wireless energy to electrical energy and storing the energy. Leysieffer et al. teach of a fully implantable cochlear implant with a rechargeable energy source that transforms wireless energy from a wireless charging unit to electrical energy and stores the electrical energy (Column 5, Lines 24-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lue et al. to have a energy transforming device so that the implanted energy source could receive energy from a wireless source as taught by Leysieffer et al. to provide a fully implantable system.

8. Claims 93 and 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lue et al. (USPN 4,739,764) in view of Summers (USPN 3,279,996).

Regarding claims 93 and 94, Lue et al. disclose an implantable incontinence device but they lack the teaching of a soft material to cover the device. Summers teaches of a urinary incontinence device where the pressure sensor and electrical contacts are covered with a silicon rubber, comprising silicone rubber which can have a hardness less than 20 Shore, to provide



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insulation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Lue et al. to have the device covered by a soft material, as taught by Summers to provide insulation means.

*Allowable Subject Matter*

Claims 5, 13, 14, 18, 19, 36-39, 48, 61-67, 96 and 97 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

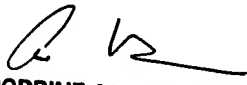
*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg  
May 27, 2003

  
CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700



UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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09/893,510

06/29/01

FORSELL

2333-72

EXAMINER

Landrem, Kamrin

ART UNIT	PAPER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Please see attached Office communication.

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## DETAILED ACTION

### *Response to Amendment*

The reply filed on October 29, 2003 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s):

#### **Revised Amendment Practice 37 CFR 1.121**

**Strict compliance is mandatory** - all amendments filed on or after July 30, 2003 must comply with the revised 37 CFR 1.121, except amendments to the specification and claims filed in reissue applications and reexamination proceedings. In reply to the Notice, applicant must submit a **corrected claim listing** that includes a proper status identifier for each claim.

The status identifier of claims 1,6,21,50,54,71, and 99, "Amended" is improper. Additionally, Claim 48 appears to be currently amended but is identified as "Original". Please review and correct if appropriate.

The seven (7) permissible status identifiers and their definitions, are:

1. (Original)
2. (Currently amended)
3. (Canceled)
4. (Withdrawn)
5. (Previously presented)
6. (New)
7. (Not entered)

See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061.

The examiner can normally be reached on 8:00-5:00, Monday-Friday.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-308-3905.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem  
Examiner  
AU 3738

KRL



David J. Isabella  
Primary Examiner